



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,036	02/20/2002	Kathleen A. Elias	CYTOP002DI	9501
22434	7590	04/02/2004	EXAMINER	
BEYER WEAVER & THOMAS LLP P.O. BOX 778 BERKELEY, CA 94704-0778			BRUSCA, JOHN S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/082,036

**Applicant(s)**

ELIAS, KATHLEEN A.

**Examiner**

John S. Brusca

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-34 and 36-45 is/are pending in the application.
- 4a) Of the above claim(s) 39-42, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-34, 36-38 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

1. The objection to the disclosure in the Office action mailed 21 October 2003 is withdrawn in view of the amendment filed 16 January 2004.

### ***Claim Objections***

2. The objection to claim 34 in the Office action mailed 21 October 2003 is withdrawn in view of the amendment filed 16 January 2004.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 24-34, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofland et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. The results are compared to a reference cell. In some embodiments, the effect of the agent is on extracellular matrix deposition, the two cells exhibit a diseased condition, and the two cells are grown in different compartments in the same medium.

Hofland et al. shows in figure 3 a visual assay of cells that were cocultured in a transwell apparatus. The cells were epithelial and fibroblast cells from human breast cancer tissue. The cells were treated with epidermal growth factor. The cells were immunostained for the presence

Art Unit: 1631

of keratin on the extracellular surface. Hofland et al. shows that epidermal growth factor and fibroblast cells enhance growth and keratin deposition in breast cancer epithelial cells. The results of Hofland et al. quantifies the amount of keratin. Hofland et al. shows in figure 3 staining of control cells with normal rabbit serum in panel b and of cocultured cells throughout.

5. Claims 24-29, 31-34, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Stearns et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The results are compared to a reference cell. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. In some embodiments, the effect of the agent is on cell shape.

Stearns et al. shows coculture of human bone marrow endothelial cells and human epithelial prostate cancer cells. The cells are treated with IL-10 in Table 2 and with antibodies to MMP-2 and MMP-9 or antibodies to TIMP-1 in Table 1. Tables 1 and 2 show the results of the cell treatment on image determined length of microvessel formation (as depicted in figure 1). Stearns et al. show in the abstract and throughout that interleukin-10 and MMP-9/MMP-2 antibodies blocked formation of microvessels in the cultured cells. Reference cell comparisons are shown in tables 1 and 2.

6. Claims 24-34, 36-38, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Zietlow et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. The results are compared to a reference cell. In some embodiments, the

Art Unit: 1631

effect of the agent is on cell viability, the two cells exhibit a neurodegenerative diseased condition, in some embodiments the cells are neurons and glial cells, in some embodiments the two cells are grown in different compartments in the same medium.

Zietlow et al. shows in the abstract and figure 1 experiments in which microglial cells and neurons are cocultured in a two-well device that shares a common culture medium. The cells are treated with FMLP. Figure 2 shows the results of imaging the cells for tyrosine hydroxylase antigen by immunofluorescent microscopy as detailed in the methods section in the first column of page 1659. Figure 2 shows the results of viability of tyrosine hydroxylase cells after the coculture experiments. Figure 2 shows comparison of the results to control cells.

### *Response to Arguments*

7. Applicant's arguments filed 16 January 2004 have been fully considered but they are not persuasive. The applicants point to preferred embodiments in which quantitative fingerprints, algorithms, and phylogenetic trees are generated, however such limitations are not in the claims and will not be further addressed.

### *Conclusion*

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1631

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is (517) 272-0714. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (517) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*JSB. Brusca 24 March 2004*  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb